

FOOD AND DRUG ADMINISTRATION

Center for Tobacco Products (CTP)

Tobacco Products Scientific Advisory Committee (TPSAC)

9200 Corporate Boulevard, Rockville, MD 20850

July 21-22, 2011

July 21, 2011 – morning session

The Committee will discuss changes proposed by Committee members to the TPSAC Menthol Report submitted to the agency on March 18, 2011. The Committee will consider additional oral and written comments from the public. The Committee will consider and deliberate on proposed changes to the report and adopt amendments that constitute the advice of the Committee.

9:00	Call to Order	Jonathan Samet, M.D., M.S. Chair, TPSAC
9:05	Conflict of Interest Statement	Caryn Cohen, M.S. Designated Federal Official, FDA/CTP
9:10	Introduction of Committee Members	
9:15	Opening Remarks	Corinne Husten, M.D., M.P.H. Senior Medical Advisor, FDA/CTP

9:30 Committee Discussion:

1. On March 23, FDA received proposed changes to the March 18 version of the Report, although the conclusions remained the same.

Please state whether you have:

- Any comments on any of the proposed changes;
- Any objections to any of the proposed changes;
- Any further changes you believe need to be made to the Report at this time.

10:00 Open Public Hearing

11:00 Committee Discussion:

2. TPSAC has received public comments on the Report since the announcement of this meeting, and the posting of the Menthol Report on the FDA website.

Please comment on:

- The information the public has provided to TPSAC in writing and at today's open public hearing;
 - What changes, if any, need to be made to the Report in light of the information presented.
3. In the Menthol Report, TPSAC made the following recommendation: "Removal of menthol cigarettes from the marketplace would benefit public health in the United States." If you agree,

please state what scientific data, information, or reasoning was particularly persuasive to you in coming to this recommendation. If you disagree, please explain your reasoning.

4. Is this Menthol Report (reflecting any and all changes made during today's meeting) your report and recommendation to FDA on the public health impact of menthol in cigarettes? (voting question)

12:00 Lunch

July 21, 2011 – afternoon session

The committee will initiate discussions on the issue of the nature and impact of the use of dissolvable tobacco products on the public health. These discussions will begin the process for the TPSAC's required report to the Secretary of Health and Human Services regarding the issue of the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children.

1:00	Call to Order	Jonathan Samet, M.D., M.S. Chair, TPSAC
1:05	Conflict of Interest Statement	Caryn Cohen, M.S. Designated Federal Official, FDA/CTP
1:10	Introduction of Committee Members	
1:15	FDA presentation: Dissolvable Tobacco Products	David L. Ashley, Ph.D. Director, Office of Science, FDA/CTP
	FDA presentation: process for the report	Karen Templeton-Somers, Ph.D. Office of Science, FDA/CTP
1:30	Industry presentations: Marketing and Consumer Perception	
	Star Scientific (up to 25 minutes)	Curtis Wright, M.D., M.P.H. Senior Vice President & Clinical Director Rock Creek Pharmaceuticals
	R. J. Reynolds Tobacco Company (up to 25 minutes)	Aaron P. Williams, Ph.D. Vice President Smokeless Product Development R. J. Reynolds
2:30	Break	
2:45	Industry presentations: Abuse Liability and Health Risks	
	R. J. Reynolds Tobacco Company (up to 25 minutes)	Charles D. Garner, Ph.D., DABT, CIH Senior Director Regulatory Oversight R. J. Reynolds
	Star Scientific (up to 25 minutes)	Curtis Wright, M.D., M.P.H. Senior Vice President & Clinical Director Rock Creek Pharmaceuticals

3:45		Break
4:00	Industry presentations: Initiation and Cessation	
	Star Scientific (up to 25 minutes)	Curtis Wright, M.D., M.P.H. Senior Vice President & Clinical Director Rock Creek Pharmaceuticals
	R. J. Reynolds Tobacco Company* (up to 35 minutes)	Geoffrey M. Curtin, Ph.D. Principal Scientist/Director Regulatory Oversight R. J. Reynolds

*Please note: As allowed, per FDA instructions for all invited industry speakers, RJRT requested and was granted any extra 10 minutes for this portion of the meeting

5:00 Adjourn

July 22, 2011

8:00	Call to Order	Jonathan Samet, M.D., M.S. Chair, TPSAC
8:05	Conflict of Interest Statement	Caryn Cohen, M.S. Designated Federal Official, FDA/CTP
8:10	Introduction of Committee Members	
8:15	FDA presentation: Dissolvable Tobacco Products	Sarah E. Evans, Ph.D. Office of Science, FDA/CTP
9:15	Committee Discussion	
9:45	Break	
10:00	Open Public Hearing	
11:00	Committee Discussion of <i>Questions to the Committee and Next Steps</i>	
12:00	Adjourn	